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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,149

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EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,149	Applicant(s) SMITH, FRANCIS X.	
	Examiner TRISTAN J. MAHYERA	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/29/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-7 are pending. Claims 1-7 are examined on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d) is acknowledged.

Specification

The disclosure is objected to because of the following informalities: The use of the trademarks COSMOCIL CQ, TETRONIC, PLURONIC, TWEEN, BRIJ, MYRJ, ATLAS, CREMPHOR and DEQUEST have been noted in this application. A trademark should be capitalized wherever one appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required.

Claim Objections

Claims 3 and 7 are objected to because of the following informalities: Regarding claim 3, a period "." occurs after sodium persulfate in the Markush group. It should be a comma ",". Regarding claim 7, no period occur after the claim, i.e. after the "20". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by MOWREY-MCKEE et al. (US 5,817,277 see PTO-892).

MOWREY-MCKEE teaches a method and solution for disinfecting contact lens comprising 0.00001 to 0.1 percent of PHMB (polyhexamethylene biguanide), which reads on 0.1 to 500ppm (0.00001 to 0.05%) of a cationic polymeric preservative and 50 to 200ppm hydrogen peroxide, which reads on 0.01 to 0.0001% (100 to 1ppm) or a peroxide producing agent. See e.g. claims 1 and 3: instant claims 1 and 3. The solution further contains a surfactant. See e.g. claim 5: instant claim 5. The solution is used on contact lens, which are in a container (i.e. vial) with a sufficient amount of the solution to cover the lens. See e.g. col. 3 line 66 to col. 4 line 4: instant claim 6. A buffer (i.e. chelating agent) is added to the solution. See e.g. claims 1, 6 and 7. The

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chelating agent (buffer) is taught to be citric acid. See e.g. col. 2 lines 50-53: instant claim 4. The buffer is further tromethamine, which is also known as TRIS buffer and is used at 0.5%, which reads on the 0.05 to 2.5 percent in instant claim 4. See e.g. claim 1: instant claim 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over MOWREY-MCKEE as applied to claims 1, 3, 4, 5 and 6 above, and further in view of OGUNBIYI et al. (US 4,758,595 see PTO-892).

MOWREY-MCKEE teaches a method and solution for disinfecting contact lens comprising PHMB (polyhexamethylene biguanide), a cationic polymeric preservative, and hydrogen peroxide, as described above.

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MOWREY-MCKEE does not explicitly teach the n value of the polyhexamethylene biguanide polymers in claims 2 (n =at least 3) and 7(n =between 5 and 20).

OGUNBIYI teaches the biguanide formula of instant claim 2, where $n=1$ to 500. See Formula (I): instant claim 2. The n is taught to preferably be from 3 to 8. See e.g. col. 3 lines 57-61: instant claims 2 and 7. These n values are taught to be most convenient when the biguanides are used with hydrochloride to give the water soluble salts. See e.g. col. 3 lines 53-61.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a ophthalmic solution comprising biguanides where the n value is taught to preferably be from 3 to 8, as taught by MOWREY-MCKEE in view of OGUNBIYI. One of ordinary skill in the art at the time the invention was made would have been motivated to uses such an n value because these values are most convenient when the biguanides are used with hydrochloride to give the water soluble salts as taught by OGUNBIYI. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 8 of copending Application No. 11/613050. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach the use of a

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peroxide producing agent, a polymeric preservative of the same formula, a surfactant, a buffer, and a contact lens vial. The applications differ because the range of the peroxide in the copending application is broader, yet fully encompassing of the instant range.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615